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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,145	02/13/2004	Joseph Schlessinger	034536-1211	5889

22428 7590 09/21/2005

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EXAMINER	
PROUTY, REBECCA E	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,145	SCHLESSINGER ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-10 have been canceled. Claims 11-16 are at issue and present for examination.

Claims 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 14 (upon which claims 12, 13, 15, and 16 depend) are indefinite in the recitation of "variant thereof" Pages 23-24 of the specification define a variant as "a molecule substantially similar to either the entire peptide or a fragment thereof" and state that variant peptides may have any combination of deletion, insertion, and substitution mutations provided that the final construct possesses the desired activity. This definition fail to clearly define the metes and bound of the term variant. How many mutations can be present and still be "substantially similar"? Gurthermore, the specification does not define even what functional activity must be maintained in a variant.

Claim 16 is incomplete as depending from cancelled claim 1. For further examination, it is presumed it was intended to depend from Claim 11.

Claims 11, 12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written

description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 11, 12 and 14-16 are directed to methods of using a genus of RPTP polypeptides and variants thereof. The specification teaches the structure of only a two representative species of such RPTP polypeptides. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of receptor protein tyrosine phosphatase activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 11, 12 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of use of the RPTP-α proteins of SEQ ID NOS: 1 and 3 or the ligand binding domain thereof, does not reasonably provide enablement for methods of using any variant thereof.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 11 is so broad as to encompass methods of identifying compounds which interact with any variant of the proteins of SEQ ID NOS:1 or 3 or the ligand biding domain thereof. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of RPTP enzymes and ligand binding domains thereof broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of a two RPTP-α proteins and comparison of the amino acid sequence of this RPTP with that of other RPTPs.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass methods of using any variant of the proteins of SEQ ID NOS:1 or 3 or the ligand biding domain thereof because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting RPTP-α activity; (B) the general tolerance of RPTP-α to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any RPTP-α residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including methods of use of any variant of the proteins of SEQ ID NOS:1 or 3 or the ligand biding domain thereof. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of variants having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11, 12, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charbonneau et al. (Reference A10) or Streuli et al. (Reference A50).

Each of Charbonneau et al and Streuli et al. teach a receptor-type PTP protein within the scope of applicants definition of a variant of SEQ ID NO:1 or 3. Therefore, one of ordinary skill in the art would have been motivated to find any compounds to which these proteins would bind as these compounds would have been reasonably expected to be ligands for the extracellular domain or other compounds which would regulate the enzymatic activity of the PTP. Methods for identifying compounds which bind to a protein of interest are well known in the art and include coprecipitation and affinity chromatography each of which comprise binding a protein of interest to a solid support, contacting the solid-support bound protein with a compound of interest, removing all unbound compound, and detecting the presence of any compound bound to the solid support. Therefore, it would have been obvious to one of ordinary skill in the art to use the RPTPs of Charbonneau et al. or Streuli et al. or the extracellular domain thereof in well known assays for identifying compounds which bind to a protein

of interest in order to identify ligands of the receptor or other compounds which regulate the activity of the R-PTP protein.

Claims 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews et al. (Reference A37).

Matthews et al. teach a mouse RPTP protein identical to SEQ ID NO :3. Therefore, one of ordinary skill in the art would have been motivated to find any compounds to which these proteins would bind as these compounds would have been reasonably expected to be ligands for the extracellular domain or other compounds which would regulate the enzymatic activity of the PTP. Methods for identifying compounds which bind to a protein of interest are well known in the art and include coprecipitation and affinity chromatography each of which comprise binding a protein of interest to a solid support, contacting the solid-support bound protein with a compound of interest, removing all unbound compound, and detecting the presence of any compound bound to the solid support. Therefore, it would have been obvious to one of ordinary skill in the art to use the RPTP of Matthews et al. or the extracellular domain thereof in well known assays for identifying compounds which bind to a protein of interest in order to identify ligands of the receptor or other compounds

which regulate the activity of the R-PTP protein. While Matthews et al. was published after the filing date of parent application 07/551,270, the current claims have not been accorded benefit of the filing date of this parent application as the parent application does not describe SEQ ID NO:1.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 10/777,186. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference

claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 11-16 herein and claim 11 of the copending application are both directed to methods of identifying a compound that interacts with a RPTP protein or the ligand binding portion thereof. The claims differ in the scope of RPTP protein or the ligand binding portion thereof encompassed by the claims and in that Claim 11 of the copending application requires the RPTP protein or the ligand binding portion thereof to be attached to a solid support while only Claim 16 herein is so limited. The portion of the specification of the copending application that supports the recited RPTP protein or the ligand binding portion thereof includes two embodiments that would anticipate all of claims 11-16 herein, e.g., SEQ ID NOS:1 and 3. Claims 11-16 cannot be considered patentably distinct over claim 11 of copending 10/777,186 when there is a specifically recited embodiment (i.e., the use of SEQ ID NOS:1 or 3, or the ligand binding domains thereof) that would anticipate claims 11-16. Alternatively, claims 11-16 cannot be considered patentably distinct over claim 11 of copending 10/777,186 when there is a

specifically disclosed embodiment in copending 10/777,186 that supports claim 11 of that application and falls within the scope of claims 11-16 herein because it would have been obvious to one having ordinary skill in the art to modify the method of claim 11 of the copending application by selecting a specifically disclosed embodiment that supports that claim, i.e., the use of SEQ ID NOS:1 or 3, or the ligand binding domains thereof. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claim 11.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on

access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rebecca Prouty
Primary Examiner
Art Unit 1652